

Status Summary

Claims 1-11 are pending in the present application and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 1-5, 9 and 10 have previously been withdrawn. Claims 6-8 and 11 presently stand rejected.

Claims 6-8 and 11 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims lack enablement.

By this Amendment, claims 6, 7, and 11 have been amended. No new matter has been added. Therefore, upon entry of the Amendment, claims 6-8 and 11 will be pending in the subject application.

Response to the Rejection of Claims Under 35 U.S.C. § 112, first paragraph

Claims 6-8 and 11 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims lack enablement. The Examiner contends that while some genetic mutations can lead to cancer, not all genetic mutations lead to cancer. Specifically, the Examiner asserts that genetic mutations can be silent mutations, can lead to cell death, or can lead to cell malignancy; therefore the correlation of just any chromosome abnormality and DNA-dependent protein kinase activity doesn't independently predict that a patient will develop cancer. Further, the Examiner contends that there is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to determine susceptibility to breast cancer, uterine cancer, or head and neck cancer by measuring DNA-dependent protein kinase

activity.

The positions of the Examiner as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claims 6, 7, and 11 have been amended to further clarify the claimed subject matter. Specifically, claims 6, 7, and 11 have been amended to recite, *inter alia*, "a method for assessing a subject's susceptibility to cancer to determine if the subject should be further screened for cancer". Additionally, claim 7 has been amended to recite, *inter alia*, "wherein a lower DNA-dependent protein kinase activity for the test subject indicates an increased likelihood of developing cancer". Support for the amendments can be found throughout the specification, including particularly in the specification as originally filed at page 16, lines 6-15 and page 22, line 9, through page 23, line 13. Thus, no new matter has been added by the amendments to claims 6, 7, and 11.

The Examiner first asserts that not all genetic mutations lead to cancer. In response, applicants respectfully submit that this contention is not controverted. Specifically, the instant methods are not reliant on the detection of individual genetic mutations and their effect on the susceptibility to cancer. Nor is it a certainty that the presence of genetic mutations will lead to the development of cancer. Rather, based on the established relationship between genetic mutations and cancer development, assessing the totality of the genetic landscape for the presence of genetic mutations based upon the level of DNA-dependent protein kinase activity provides an assessment of the likelihood that a patient will or will not develop cancer. Applicants respectfully submit that classifying a subject as susceptible to cancer based upon low

DNA-dependent protein kinase activity does not guarantee that the subject will develop cancer; but rather, it suggests that the subject is more likely to develop cancer than a subject with normal DNA-dependent protein kinase activity. Thus, the methods of the presently claimed subject matter are directed to the assessment of the overall level of genetic mutations, as indicated by DNA-dependent protein kinase activity, which is indicative of a subject's susceptibility or likelihood of developing cancer.

Further, applicants respectfully submit that the amended claims are not directed to methods of predicting that a patient will develop cancer, as asserted at page 3 of the Official Action. Rather, applicants respectfully submit that the amended claims are directed to methods of assessing a subject's susceptibility to cancer to determine if the subject should be further screened for cancer. In particular, claims 6, 7, and 11 have been amended to recite, *inter alia*, "to determine if a subject should be further screened for cancer". As such, the intention of the presently claimed subject matter is not to predict that a subject will develop cancer, but rather, to provide a method of screening subjects to determine if, based upon DNA-dependent protein kinase activity, a patient is more or less likely to develop cancer. If, for example, an assessment of a subject's susceptibility to cancer suggests he or she is likely to develop cancer, then further cancer screening may be employed by a medical practitioner to clarify the subject's cancer risk. See, for example, page 16, lines 6-15 of the specification. As such, one of skill in the art would understand that the instant claimed methods are designed to be a screening method to separate subjects based upon their susceptibility or likelihood of developing cancer. The

advantage of such a method is that it provides patients and medical practitioners with a screening and early detection tool for cancer susceptibility.

Applicants respectfully disagree with the Examiner's contention that the specification does not provide any direction or guidance to assist one skilled in the art in the determination of susceptibility to cancer before the patient has the cancer. Initially, applicants note Figure 1, which illustrates that chromosome abnormalities are inversely related to DNA-dependent protein kinase activity. As would be appreciated by one of skill in the art, chromosome abnormalities are the result of damages to DNA molecules that result in genetic mutations. Accordingly, the accumulation of genetic mutations can lead to malignant transformations in cells, resulting in cancer. See, for example, page 7, lines 8-17 of the specification. Further, DNA-dependent protein kinase plays a role in preventing genetic mutations and chromosome abnormalities. See, for example, page 3, lines 6-13. Therefore, a decrease in DNA-dependent protein kinase activity that results in an increase in chromosome abnormalities can result in increased susceptibility to cancer. As such, a subject with decreased DNA-dependent protein kinase activity, determined in accordance with the presently disclosed subject matter, is susceptible to, or has an increased likelihood of, developing cancer due to an increased potential to develop genetic mutations. See page 15, line 10, through page 16, line 15.

Thus, since it is established that DNA-dependent protein kinase is inversely related to genetic mutations and that genetic mutations can lead to cancer, it is axiomatic that prior to the development of cancer resulting from genetic mutations there must have been present one or more genetic mutations. Stated another way,

cancer resulting from one or more genetic mutations cannot develop unless there is first a genetic mutation. Further, based upon the established relationship discussed hereinabove, if genetic mutations are present it is likely that the mutations are due, at least in part, to reduced DNA-dependent protein kinase activity. As such, one of skill in the art will appreciate that the relationship between cancer, genetic mutations and DNA-dependent protein kinase activity exists both pre and post-cancer development.

Finally, the Examiner asserts that there is no evidence provided to assist one of skill in the art in determining how far in advance of the cancer diagnosis the abnormal kinase activity is present. In response, applicants respectfully submit that the amended claims are directed to methods of assessing a subject's susceptibility to cancer based upon DNA-dependent protein kinase activity. Thus, the claimed methods are not meant to diagnose cancer, although the detection of low DNA-dependent protein kinase activity may, in some cases, lead to the diagnosis of cancer in a subject. Therefore, the claimed methods, as would be appreciated by one of skill in the art upon review of the instant disclosure, are designed to be employed at any time during the subject's life. To elaborate, the claimed methods provide a "snapshot" of the subject's level of genetic mutations at one particular moment in time. This "snapshot" of the subject's level of genetic mutations provides an estimate of the subject's susceptibility to developing cancer based upon the DNA-dependent protein kinase activity at that time. One of skill in the art will understand that detection of normal DNA-dependent protein kinase does not guarantee that the subject will never develop cancer; but rather, that the subject is at that time not susceptible or likely to develop cancer. Stated another way, a patient with

substantially normal DNA-dependent protein kinase activity would not be classified as high-risk regarding cancer development and would therefore not need to be subjected to further cancer screenings. Alternatively, one of skill in the art will understand that the detection of an abnormally low level of DNA-dependent protein kinase activity in a subject simply means that they are more susceptible or more likely to develop cancer at some point in the future. This information would provide a medical practitioner the opportunity to engage in further cancer screenings to allow for preventative or proactive cancer therapies. Thus, the timing of the assessment of a subject's susceptibility to cancer is irrelevant, as the methods are designed to provide one of skill in the art a method to separate patients that need further cancer screening from those that do not.

Accordingly, applicants respectfully submit that claims 6-8 and 11 are enabled by the specification in accordance with 35 U.S.C § 112, first paragraph, regarding the ability to assess a subject's susceptibility to cancer to determine if the subject should be further screened for cancer. Thus, applicants respectfully request that the rejection of claims 6-8 and 11 under 35 U.S.C. § 112, first paragraph, be withdrawn, and request that claims 6-8 and 11 be allowed at this time.

CONCLUSION

In light of and upon entry of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

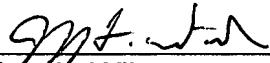
Although it is believed that no fee is due, The Commissioner is authorized to charge any deficiencies of payment associated with the filing of this correspondence to Deposit Account No. 50-0426 to avoid the unintentional abandonment of the instant application.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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